Hyaluronic acid gel improves wound healing in diabetic patients after digit amputations

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PURPOSE

Foot ulceration and amputation are common, multi-factorial and costly complications in patients with diabetes [1-3]. Upwards of 85% of amputations are preceded by foot ulcers [3], and those patients with a lower extremity amputation have a diminished quality of life [4]. The healing of digit amputations is not often predictable and its complications are an important cause of morbidity and mortality in patients with diabetes [5]. In recent years, major advances in wound treatment have developed, however, a high prevalence of non-healing wounds still persists. Therefore, it is vital to treat these wounds with advanced wound dressings that can accelerate wound healing and decrease comorbidities.

The purpose of this study was to evaluate the time to heal in diabetic patients with digit amputations treated with a sodium hyaluronate (2.5%) wound gel [6] from January 1st to July 31st, 2015.

METHODS

After digit amputations, patients received the hyaluronic acid gel treatment daily until incision line was healed. Every week, photographs of incision lines were taken. Time to heal for surgical incisions was defined as the time it took for the sutures to be removed.

RESULTS

Our results demonstrated that the time to heal in those patients receiving hyaluronic acid gel after performing digit amputations was predominantly within 2 weeks. This is in contrast to a typical 4 week healing time that we observed prior to using HA gel. In addition, our complication rate was correspondingly low as we were not dealing with incision line dehiscence or infection.

CONCLUSIONS

The results showed that HA gel may improve the time to heal of the incision lines compared to those treated with standard of care and reduces complication rates by introducing this product as a postoperative treatment protocol.

ACKNOWLEDGEMENTS

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References

6. IPM™ Wound Gel Bio
The Use of 2.5% Sodium Hyaluronate Wound Gel to Promote Wound Healing for Patients with Diabetic Foot Ulcers (DFUs) and Lower Leg Ulcers (LLUs) in Community Settings by a Certified Wound Ostomy Continence Nurse (CWOCN)

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**Background**
- Reducing health care costs has been acknowledged as a global issue.
- “Every 30 seconds a lower limb is lost due to diabetes somewhere in the world”.
- 50% patients with leg ulcers had a leg ulcer history 5 to 10 years; 30% > 10 years.
- Treatment costs increases when the duration of treatment, and product use increase.
- Early identification of difficult-to-heal wounds and targeted use of advanced wound care products should be considered whenever possible (Vowden 2011).

**2.5% Sodium Hyaluronate Wound Gel**
Has been used for management of lower leg ulcers, pressure ulcers, diabetic foot ulcers, and surgical wounds (Reece & Quiring, 2002; Woo, et al 2005).

**Method (Study period: May – November 2016)**
This prospective, self-controlled non-randomized clinical case series study was conducted to evaluate the efficacy of 2.5% sodium hyaluronate wound gel for community patients with DFUs or LLUs in out-patient clinic settings by assessing:
- The healing rates by comparing the changes of wound size and time to heal
- The incidence of complications

**Inclusive Criteria**
- Wounds that failed to reduce size by 30% after treatment for 4 weeks
- DFU: of wound size <10 cm²; have been off-loaded with most appropriate offload device, Total Contact Cast (TCC), Poor Man TCC, iTCC, etc.
- LLUs of wound size <100 cm²
- Patient with LLUs that have been on 20 mmHg or more compression therapy

**Study Protocol (Weekly wound gel treatment till wound closed or a max. 27 weeks)**
- Sharp or mechanical wound debridement by the Principal Investigator, a CWOCN
- Applied wound gel liberally to wound base and margins
- Maintained moisture/bacterial balance with bacterial binding dressings to
- Continued with appropriate offload (DFUs) or compression (LLUs)

**Results:**
- 33 patients recruited; 20 patients completed the study (10 DFU (50%); 10 LLUs (50%):
- 8 patients (40%): wounds closed
- 9 patients (45%): wounds improved
- 3 patients (15%): wound status undetermined
- Mean Home Care Nurse treatment days before PI treatment: 195 days
- Mean PI treatment days before wound gel treatment: 193 days
- Mean wound gel weekly applications 15 weeks (105 days)

**Implications:**
1. The results supported the use of the wound gel to supplement standard wound treatment for patients with DFUs or LLUs.
2. To provide stronger evidence, further studies with a larger sampling size with follow up assessments in 3, 6 and 12 months to evaluate the recurrence rates is recommended.

**References:**

**Disclaimer**
- This study was unfunded. The vendor provided the 2.5% sodium hyaluronate wound gel for 20 selected patients for product evaluation.
- The trade name of this 2.5% sodium hyaluronate wound gel is GlycoBioSciences Inc. IPM™ Wound Gel Bio.